Zinc Borate
Interim Registration Review Decision
Case Number: 5025

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Approved by: A Pease

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Director
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I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for zinc borate (PC Code: 128859) and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on zinc borate can be found in the Agency's public docket (EPA-HQ-OPP-2007-0675) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the Agency based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The Agency is issuing an ID for zinc borate so that it can move forward with aspects of the registration review that are complete. The Agency determined that no pollinator exposure and effects data are necessary to make a final registration review decision for zinc borate. The Agency has evaluated risks to listed species and is making a "no effects" finding for listed species and designated critical habitat and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under the Endangered Species Act (ESA) section 7(a)(2) is not required. The Agency will complete endocrine screening for zinc borate, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), before completing registration review. See Appendices D and E, respectively, for additional information on the endangered species assessment and the endocrine screening for the registration review of zinc borate.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of any public comments received on the draft risk assessment and the Agency's responses; *Usage Information*, which describes how and why zinc borate are used; *Scientific Assessment*, which summarizes the Agency's risk assessments; the *Interim Registration Review*

Decision, which describes the regulatory rationale for the Agency's registration review decision; and, lastly, the *Next Steps and Timeline* for completion of this interim registration review.

A. Updates Since the Proposed Interim Decision was Issued

The zinc borate ID reflects updates since the Proposed Interim Decision (PID) regarding proposed mitigation first introduced in the PID. The original proposed mitigation and the benefits assessment for zinc borate have been revised based on comments received during the PID public comment period and through additional correspondence between EPA and the U.S. Forest Service, respectively.

The PID for zinc borate stated, "Super sack bag handlers involved in opening, moving, hanging, or disposing of the super sack must wear respirators". Prior to opening, the super sacks are sealed double bags that are relocated from storage to the area of use. The workers that move the sacks are moving unopened sacks, and they do not need to wear a respirator. The term "moving" has been removed from the respirator scenario. This language has been removed from the required label mitigation, as shown in Appendix B. Additionally, a statement was added in to clarify that once engineering controls are implemented, the respirator requirement for handlers of super sacks will no longer be required.

The wood preservative labeling requirements discussed in Section III.A. and Appendix C have also been updated. As described further in Section III.A and Appendix C, the retention rate will no longer be required on the label except in limited circumstances and the application rate requirement has been clarified. These changes are consistent with the Agency's requirements for other wood preservative cases.

Additionally, the PID stated that zinc borate is the "only viable alternative" for preserving composite wood exposed in outdoor applications. The U.S. Forest Service clarified, for the record, that zinc borate is the primary preservative used in products like oriented strand board (OSB) and composite wood siding products.[1] Therefore, the Agency has revised the benefits discussion in this Interim Decision for zinc borate.[2]

B. Summary of Zinc Borate Registration Review

Pursuant to 40 CFR section 155.50, the Agency formally initiated registration review for zinc borate (PC Code: 128859). The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of zinc borate:

[1] Email correspondence from U.S. Forest Service to Stephen Savage on September 6, 2018.
[2] The Forest Service further stated that the term "wood composites" is more widely applied to "structural" wood composite products such as plywood or glue-laminated beams. Those products are not treated with zinc borate. Instead they are pressure-treated with liquid preservatives like waterborne copper systems or oil-based copper naphthenate or pentachlorophenol. The difference is in the dimensions of the wood used, where the products treated with zinc borate tend to be flakes, strands or particles where powdered zinc borate can be added to the furnish before they are pressed into boards.

- September 26, 2012 – The Zinc Borate Preliminary Work Plan (PWP) was published to docket EPA-HQ-OPP-2007-0675 for a 60-day public comment. The public comment period closed November 26, 2012.

- February 20, 2013 – The Final Work Plan (FWP) for zinc borate was published to docket EPA-HQ-OPP-2007-0675. During the PWP 60-day comment period, two comments were received from the public. The comments did not change the data needs, planned risk assessments, or the timeline for the registration review case; thus, the FWP did not modify the PWP.

- December 22, 2016 – The Amended Final Work Plan was completed and published to docket EPA-HQ-OPP-2007-0675. The Amended FWP removed the previously anticipated 835.6200 aquatic field dissipation data requirement. All other elements of the Agency's zinc borate FWP remained unchanged.

- December 29, 2016 – A Generic Data Call-In (GDCI) for zinc borate was issued for data needed to conduct the registration review risk assessments. All data that were required by the GDCI have been waived and the GDCI is satisfied.

- May 25, 2018 – The Draft Risk Assessment (DRA) for zinc borate was published to docket EPA-HQ-OPP-2007-0675 for a 60-day public comment period. One comment was received. The comment did not change the risk assessments or registration review timeline.

- December 31, 2018 – The *Zinc Borate Proposed Interim Registration Review Decision* for zinc borate was published to docket EPA-HQ-OPP-2007-0675 for a 60-day public comment period. Two comments were received. The comments did not change the risk assessments or registration review timeline but did inform the change in mitigation noted in Section I.A. The comments are described below along with the Agency's responses.

C. Summary of Public Comment on the Proposed Interim Decision and Agency Responses

During the 60-day public comment period on the zinc borate PID, which opened December 31, 2018 and closed on February 4, 2019, the Agency received two comments. These comments can be found in their entirety in the zinc borate docket (EPA-HQ-OPP-2007-0675). The comments addressed occupational exposure risk, toxicity uncertainty factors, the use of respirators for occupational exposure risk reduction, engineering controls, and benefits. The responses to the comments, which are shown below, did not result in a change in the Agency's risk conclusions.

Comments Submitted by Lords Additives on January 25, 2019 in EPA-HQ-OPP-2007-0675

Comment:

The registrant requested that the N95 respirator protection factors (PFs) be modified to 1100X for ZB-Shield in super-sacks and 475X for ZB-SHIELD in 25 kg bags based on the particle size distributions. They cite two studies (Cho, 2010a[3]) and (Cho, 2010b[4]) where laboratory manikin testing and field testing on human volunteers indicated that the protection factor increased with increasing particle size. In Cho 2010b, the geometric mean workplace protection factor (WPF) measured on 22 workers wearing N95 filtering face piece respirators was 67, 124, 312, 909, and 2089 for 0.7 to 1.0, 1.0 to 2.0, 2.0 to 3.0, 3.0 to 5.0 and 5.0 to 10.0 micron particles, respectively. The 5th percentile workplace protection factor measured in the same study was 16.2, 32.2, 48, 86, and 223.4, respectively.

The registrant cites the *Assigned Protection Factors: Final Rule* published by the Occupational Safety and Health Administration (OSHA) in the Federal Register on August 24, 2006 which set the Assigned Protection Factor (APF) of 10 for both the filtering facepiece and elastomeric respirators. This APF was based on 1339 WPF measurements from 20 literature studies of half mask respirators of which 760 measurements were for filtering face piece respirators and 579 measurements were for elastomeric face piece respirators. The geometric mean WPF was 307 and the fifth percentile value was 14.7.

Agency Response:

The Agency acknowledges that additional studies on respirator protection factors (e.g., Cho (2010a) and Cho (2010b)) have been published since the APF of 10 was finalized by OSHA in 2006 and that some of this research has been conducted or supported by the National Institute of Safety and Health (NIOSH) which is the research arm of OSHA. If either NIOSH or OSHA changes the APF of 10 based on this new research, the Agency will consider using the new APF in pesticide risk assessments. Although the APF of 10 is based on the 5th percentile of WPFs, the Agency is not planning to use APFs that are based on other values, such as the geometric mean, at this time. This would be inconsistent with the APF that was selected by OSHA after the extensive literature review and rulemaking process that is detailed in OSHA Docket H049C on www.regulations.gov.

Comment Submitted by US Borax in EPA-HQ-OPP-2007-0675

US Borax requested that the Agency refine/revise the inhalation risk assessment in three ways listed below as comment 1 parts a, b, and c.

Comment 1a: Use of the MPPD Model

[3] Cho, 2010a.Large Particle Penetration through N95 Respirator Filters and Facepiece Leaks with Cyclic Flow. , Cho, K.J., Reponen, T., McKay, R., Shukla, R., Haruta, H., Sekar, P., and Grinshpun, S.A., Annuals of Occupational Hygiene Vol. 54, No. 1, pp 68-77. 2010

[4] Cho, 2010b. Effect of Particle Size on Respiratory Protection Provided by Two Types of N95 Respirators Used in Agricultural Settings. Cho, K.J., Jones, S., Jones, G., McKay, R., Grinshpun, S. A., Dwivedi, A., Shukla, R., Singh, U., Reponen, T., Journal of Occupational and Environmental Hygiene, Volume 7, pp 622-627. November 2010

Increase the Human Equivalent Concentration (HEC) value from 0.71 to 4.5 mg/m^3 by using the Multiple Path Particle Dosimetry (MPPD) model for HEC calculation instead of the Regional Dose Deposition Ratio (RDDR) model used by the Agency for the HEC calculation.

- Basing the HEC on nasal degeneration heavily skews the HEC on a limited effect that does not produce functional impairment in olfactory epithelium. The nasal degeneration was only observed in olfactory epithelium, with minimal to mild effects at exposures less than 75 mg/m^3. The HEC should be based on effects in the lung relevant to humans showing functional impairment.
- The RDDR uses the rat model and the MPPD uses rat and human respiratory tracts.
- Use of the rat model relies on nasal effects which were seen as a lower concentration than all respiratory tract effects.

Agency Response 1a:

The Agency calculated RDDRs using the RDDR Software Program with inputs of 2.1 microns for the Mass Median Aerodynamic Diameter (MMAD), 2.6 for sigma g and 250 grams for the rat body weight. The resulting RDDRs were 0.19 for the extrathoracic (ET) region, 1.1 for the tracheobronchial region, 0.48 for the pulmonary region, 0.681 for the thoracic region and 1.6 for the total respiratory tract. The Agency chose the RDDR of 0.19 for the ET region to calculate the HEC of 0.71 mg/m^3 because effects were seen in this region and the RDDR for the ET region is protective of the effects that were seen in the pulmonary region. If effects had only been seen in the pulmonary region, the Agency would have used the RDDR of 0.48 for the pulmonary region to calculate an HEC of 1.8 mg/m^3.

The Agency is aware that the MPPD model can be used to calculate RDDRs for research purposes, and that some parts of the Agency, such as the Office of Research and Development, have used the MPPD Model in published papers such as the one cited by US Borax (Kuempel, 2015). However, OPP is opting to not use the MPPD model for regulatory purposes at this time because it has not been subject to OPP peer review. Peer review is required of all models that are used for risk assessments that are conducted by OPP.

Comment 1b:

Decrease the intraspecies uncertainty factor from 10x to 5x because worker populations are healthier and more homogenous than the General Population.

Agency Response 1b:

The Agency does reduce the intraspecies uncertainty factor in some instances specific to particular chemical characteristics and agrees that the industrial worker population generally does not include the elderly and children. However, reducing the intraspecies safety factor for zinc borate would require consideration of the chemical characteristics and further analysis of the workforce. The registrant did not provide substantive scientific justification to warrant factor reduction for this assessment.

Comment 1c:

Decrease the database uncertainty factor from 10x to 3x by bridging between the zinc oxide 14-day inhalation study, zinc oxide 90-day inhalation study and the zinc borate 14-day inhalation study and the zinc borate 90-day oral study. Since zinc oxide and zinc borate are structurally similar and the effects seen in the studies are the same, the data can be bridged.

Agency Response 1c:

The Agency does not have a 14-day inhalation zinc oxide study. The only acceptable inhalation data are from the 14-day zinc borate and the 90-day zinc oxide studies. As US Borax noted, the Hazard and Science Policy Committee (HASPOC) considered whether the 90-day inhalation study should be waived for zinc borate and determined that the study was needed since some of the potential effects seen in the 14-day inhalation study may worsen over a longer exposure.

US Borax stated that the 90-day oral study did not show the liver and bone effects that were potentially flagged in the 14-day inhalation study; however, the effects from the oral dosing are different than those seen by the inhalation route and toxicity occurs at a lower dose by the inhalation route. Therefore, the Agency has determined that it is not appropriate to reduce the database uncertainty factor from 10x to 3x in the absence of a longer-term inhalation study on zinc borate.

Comment Submitted by US Borax in EPA-HQ-OPP-2007-0675

US Borax also commented on who should be included in wearing the PF 10 respirator. The PID stated, "Super sack bag handlers involved in opening, moving, hanging, or disposing of the super sack must wear" respirators. US Borax affirmed that the term "moving" should be removed from the respirator scenario, stating, "Prior to opening, the super sacks are sealed double bags that are only relocated from storage to the area of use. Moreover, 'moving' could also be interpreted as covering the offloading of super sacks during delivery. Since it is highly unlikely that any inhalation exposure will result from the movement of super sack bags, there is no need for workers that perform this task to wear respirators."

Agency Response:

The Agency concurs that the term "moving" should be removed from the respirator scenario for mitigation. The workers that move the sacks are moving unopened sacks and they do not need to wear a respirator. This language has been removed from the required label mitigation, as shown in Appendix B.

D. Usage Information

There are currently six registered products (EPA Reg. Numbers 1624-120, 1624-131, 73032-1,73032-3, 83933-2, 89807-1) containing the active ingredient, zinc borate. These products are registered for use as materials preservatives and wood preservatives for wood composite materials. The labels for the zinc borate products require the mixing of the product within an onsite feeder/delivery system. Labels require that the zinc borate loading in wood products must

not exceed 8% (w/w). The products are packaged in multiwall paper bags (50 lbs. net weight) or super-sacks (2,500 lbs. net weight). Zinc borate products are also registered for use to preserve plastic and rubber items. Zinc borate products are also registered for use to preserve interior products including poly vinyl chloride (PVC) carpet backing, wall coverings, auto upholstery, shower curtains and urethane mattresses as well as outdoor products including polyolefin wire and cables, PVC tenting and awnings. Zinc borate is also registered for use (Reg. No. 83933-2) as a paste formulation that is applied at the ground line to utility poles, timber structure and railway ties. It can be applied as a surface treatment using a brush, trowel or bandage or it can be applied into drilled holes using a caulking gun. The package size ranges from 10.1 ounces to 44 pounds. There are no registered direct or indirect food uses for zinc borate.

II. Scientific Assessments

A. Human Health Risk

A summary of the Agency's human health risk assessment is presented below in support of the registration review of zinc borate. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of zinc borate. Toxicological Point of Departures (PODs) are presented in the Draft Risk Assessment. For detailed discussions of all aspects of the human health assessment, see the *Registration Review Preliminary Risk Assessment for: Zinc Borate* located in the public docket EPA-HQ-OPP-2007-0675 at www.regulations.gov.

1. Summary of Human Health Risks and Risk Characterization

The Agency has determined that there are potential inhalation risks of concern for occupational handler exposure while unloading 2,500 lbs. super sacks in wood composite manufacturing sites (see Section 3, "Occupational Risks," below for details). Furthermore, risks to residential handlers and post application exposures from the use of zinc borate were assessed and are not of concern (see the Draft Risk Assessment for Zinc Borate for details).

Dietary Exposure/Tolerances

There are no direct food or feed uses for zinc borate; therefore, the Agency has not established tolerances or exemptions from tolerances in raw agricultural commodities or processed food and feed products under the Federal Food, Drug and Cosmetic Act (FFDCA). The labels for zinc borate prohibit food use. Therefore, no dietary assessment is necessary.

A dietary (food and drinking water) exposure assessment is not currently required for zinc borate. The FIFRA registered uses of zinc borate are not expected to result in direct or indirect dietary (food) exposure. The use of zinc borate products is not expected to pose a hazard to groundwater or surface waters; therefore, a drinking water assessment is not currently required.

Aggregate Exposure

An aggregate exposure risk assessment was not conducted for this chemical because of a lack of dietary and drinking water exposure.

Cumulative Risks

The EPA has not made a common mechanism of toxicity to humans finding as to zinc borate and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, the EPA has not assumed that zinc borate has a common mechanism of toxicity with other substances for this assessment.

Occupational Risks

Inhalation MOEs for occupational exposure to powder products for composite wood and material preservation were calculated using an industrial hygiene study of a composite wood manufacturing facility (MRID 48833021) during which zinc borate air concentrations were measured during the handling of zinc borate powder in super sacks. The inhalation MOEs range from 0.9 to 44, depending on the level of respiratory protection used, and are below the target LOC of 300 indicating risks are of concern even when the highest level of respiratory protection is worn.

2. Human Incidents

No zinc borate related incidents have been reported in the Agency's Incident Data System (IDS) for the period from 1992 to March 3, 2018. The IDS contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.

3. Human Health Data Needs

The Agency does not anticipate any further human health data needs for the zinc borate registration review.

B. Ecological Risk

A summary of the Agency's environmental risk assessment is presented below in support of the registration review of zinc borate. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of zinc borate. For detailed discussions of all aspects of the ecological assessment, see the *Registration Review Preliminary Risk Assessment for: Zinc Borate* located in the public docket EPA-HQ-OPP-2007-0675 at www.regulations.gov.

1. Risk Summary and Characterization

Based on the labeled use patterns of registered products, zinc borate environmental exposure is expected to be low and to be indistinguishable from background levels of zinc and borate. Due to a lack of exposure and low toxicity, zinc borate is not expected to cause adverse effects to

nontarget organisms, including listed species and designated critical habitat. Therefore, the Agency is making a "no effect" finding for listed species based on the use of zinc borate on indoor building surfaces and as a wood preservative. Also, the Agency has determined that risks to pollinators are not expected due to the lack exposure. No additional pollinator exposure and effects data are necessary to make a final registration review decision for zinc borate.

The zinc borate environmental fate data requirements are satisfied with data from zinc borate and zinc salts.[5,6] The zinc borate data include literature studies and American Wood Protection Association (AWPA) wood leaching studies. Zinc borate immediately dissociates to form zinc hydroxide and boric acid, and as a result, the data from zinc salts are bridgeable to zinc borate because they also dissociate to form zinc hydroxide and the associated counter ion. Zinc borate and zinc salts do not undergo abiotic or biotic degradation because they are inorganic salts. Based on similar chemistry and study results, bridging between zinc salts and zinc borate is appropriate.

Based on the registered uses, exposure to microorganisms in wastewater treatment plants (WWTPs) is possible. However, zinc borate and zinc salts do not appear to cause toxicity to microorganisms in wastewater treatment plants (WWTPs) based on Activated Sludge Respiration Inhibition (ASRI) values. The parent compound, zinc borate, is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act. In addition, no Total Maximum Daily Loads (TMDL) have been developed for zinc borate.

Based on zinc borate's physical and environmental fate properties, there are no expected risks of concern and no further data are required at this time.

2. Ecological Incidents

The Agency's Incident Data System (IDS) database was checked on 3/8/2018 and no reported incidences for zinc borate were found dating back to 1992.

3. Ecological and Environmental Fate Data Needs

There are no data gaps for any of the ecotoxicity data requirements, and the Agency does not anticipate any further ecotoxicity data needs for the zinc borate registration review.

C. Benefits Assessment

According to information provided by zinc borate registrants and the U.S. Forest Service, zinc borate is the primary preservative used in products like oriented strand board (OSB) and composite wood (flakes, strands, or particles, not plywood or glu-laminated beams) siding

[5] December 12, 2012 Amended Final Work Plan for zinc salts
[6] Zinc salts include the compounds Zinc oxide (088502), Zinc metal (129015), zinc chloride (087801), zinc sulfate (089001), and zinc sulfate monohydrate (527200).

products.[7] It is the only preservative listed for that purpose in the American Wood Protection Association standard (AWPA Processing and Treatment Standard, Section J: Non-pressure Treated Wood Composites). Specifically, zinc borate is used for strand-based wood composites like OSB (Oriented Strand Board) and LSL (Laminated Strand Lumber), which cannot be preserved with waterborne copper-based preservatives.[8] Other wood preservative active ingredients are not compatible with the high-temperature process to manufacture composite wood products, like decks and siding. Other benefits of using zinc borate to preserve composite wood include cost-effectiveness, compatibility with composite wood manufacturing adhesives, resistance to leaching and weathering, flame retardant properties, and its effectiveness against termites in addition to decay.[9]

The Agency notes that copper naphthenate is an active ingredient currently registered for composite wood use. However, as described in the *Naphthenate Salts Proposed Interim Registration Review Decision* (docket EPA-HQ-OPP-2010-0455 at www.regulations.gov), the registrants informed the Agency that the composite wood use is insignificant for their products and that they intend to remove the use from the copper naphthenate labels.

III. Regulatory Rationale and Interim Registration Review Decision

A. Risk Mitigation and Regulatory Rationale

In the DRA for zinc borate, the Agency determined that there are potential inhalation risks of concern for the occupational handler exposure scenarios involving open pouring and emptying of 2500 lbs. super sacks into a composite wood machine. Therefore, the Agency is requiring labeling changes for the open pouring and emptying of 2,500 lbs. super sacks for the occupational handler inhalation exposure scenario.

In the *Registration Review Preliminary Risk Assessment for: Zinc Borate*, the Agency determined that there are no ecological risks of concern for the uses of zinc borate. Therefore, ecological risk mitigation measures are not needed at this time.

Furthermore, the Agency is requiring that zinc borate labels, which reference the American Wood Protection Association (AWPA) standards, cite the specific AWPA standard as well as the standard's publication date. The application method(s), specific wood commodities (e.g. building poles, guardrail posts, trusses, etc.), maximum rate(s) of application, and minimum retention rate for efficacy claims for pressure treatment uses are to be listed on the label. This is consistent with labeling changes the Agency is requiring for other wood preservative cases (see Appendix C).

1. Human Health Risk Mitigation Measures

The Agency worked with zinc borate registrants to address occupational inhalation risk. To mitigate the risk, the Agency is requiring respiratory protection with a Protection Factor (PF) of

[7] Zinc Borate Use Sites email from Eliot Harrison September 9, 2018 received on the uses of zinc borate in Docket EPA-HQ-OPP-2007-0675-0023
[8] Email correspondence from the United States Forest Service to Stephen Savage on February 6, 2019
[9] USDA Forest Service - email from Stan Lebow September 6, 2018

10 for handlers involved in openings. The PF 10 respirator requirement will expire on January 1, 2022 and be replaced by the requirement for remotely operated engineering controls for the application of zinc borate from super sacks. The delay in requiring engineering controls allows time for registrants to develop and implement new technology for the closed loading of zinc borate. While closed loading of liquid pesticides is common, zinc borate is formulated as a powder. According to zinc borate registrants, mechanisms for closed loading of zinc borate powder may take until to January 1, 2022 to develop and implement in all the plants where zinc borate is used as a pesticide.

Although PF10 respirators do not result in risk estimates below the Agency's level of concern, the Agency believes that they will achieve significant reduction of inhalation exposure while the registrants develop engineering controls for the closed loading of zinc borate. The Agency considered requiring respiratory protection with a PF50; however, in discussions with the registrants, it was agreed that the PF10 respirator requirement could be implemented more quickly, and therefore would be more beneficial in reducing exposure in the interim. When fully implemented, the Agency anticipates the closed loading engineering controls will reduce the occupational inhalation risk to a level that is no longer of concern.

2. Interim Registration Review Decision

In accordance with 40 CFR sections 155.56 and 155.58, the Agency is issuing the *Zinc Borate Interim Registration Review Decision*. Except for the Endocrine Disruptor Screening Program (EDSP), the Agency has made the following Interim Registration Review Decision: (1) no additional data are needed at this time, and (2) changes to the affected registrations and their labeling are needed at this time.

In this *Zinc Borate Interim Registration Review Decision*, the Agency has made a "no effect" determination under ESA for zinc borate. The Agency is making no human health or environmental safety findings associated with the EDSP screening of zinc borate. The Agency's final registration review decision for zinc borate will be dependent upon an EDSP FFDCA section 408(p) determination.

IV. Next Steps and Timeline

A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the Zinc Borate Interim Registration Review Decision. A Federal Register Notice will announce the availability of this Interim Decision. The Agency determined that no pollinator exposure and effects data are necessary to make a final registration review decision for zinc borate. As indicated in Appendix D, the Agency has made a "no effect" determination under ESA for zinc borate, and in Appendix E, the Agency's final registration review decision for zinc borate will be dependent upon the result of the EDSP FFDCA section 408(p) determination.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, zinc borate registrants are required to submit amended labels that include the label changes described in Appendices A, B, and C. The amended labels will be required to be submitted to the Agency for review within 60 days following issuance of the Interim Registration Review Decision.

V. Appendices

Appendix A: Summary of Required Actions for Zinc Borate

Registration Review Case: 5025 PC Code: 128859 Chemical Type: Wood and materials preservative					
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Required Label Changes**
Occupational handlers	Dust	Inhalation	Sub-chronic	Inhalation effects	Add PPE
					Add engineering controls for closed loading

Appendix B: Required Labeling Changes for Zinc borate

Description	Required Amended Label Language for End-Use Products	Placement on Label
Respiratory protection and engineering controls for occupational handlers using zinc borate super sacks for EPA Registration Numbers: • 1624-120 • 1624-131 • 73032-1 • 73032-3 • 89807-1	"PERSONAL PROTECTIVE EQUIPMENT: Super sack bag handlers involved in opening must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters. As of January 1, 2022, the application of zinc borate from super sacks must be accomplished with remotely operated engineering controls that achieve closed loading of zinc borate powder. Once engineering controls are implemented, respirators for handlers of zinc borate super sacks will no longer be required."	Precautionary Statements under the heading "Personal Protective Equipment"

Appendix C: Information Required to be Provided on All Zinc Borate Product Labels

The Agency requires that the following information be provided on all zinc borate labels with wood preservative uses:

- Application method(s)
- Use site/Specific wood commodities (e.g. composite siding, window casement material, outdoor applications etc.)
- Maximum rate of application
- Retention rates for products with efficacy claims on the label[10]
- If the product label references American Wood Protection Association (AWPA) standards, the label must cite the specific AWPA standard and the standard's publication year, e.g. "U1-17".

[10] A minimum retention rate will be required on the label only when the label has efficacy claims for treatment against specific organisms (e.g. termiticide and insecticide), or in cases which the retention rate is equal to 100% of the application rate.

Appendix D: Endangered Species Assessment

The Agency has no expectation for the registered pesticide uses of zinc borate to cause direct or indirect adverse effects to threatened and endangered species. The Agency has made a "no effect" determination for zinc borate for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required.

Appendix E: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the Agency reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, the Agency evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for zinc borate, the Agency reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), zinc borate is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The Agency has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where the Agency will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, the Agency issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[11] and includes some pesticides scheduled for registration review and chemicals found in water. Zinc borate is not currently scheduled for screening. However, it should be noted that zinc borate will be screened for its potential to interact with the endocrine system. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[12]

In this interim decision, the Agency is making no human health or environmental safety findings associated with the EDSP screening of zinc borate. Before completing the registration review for zinc borate, the Agency will make an EDSP FFDCA section 408(p) determination.

[11] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[12] http://www.epa.gov/endo/